DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 1, 2016

Aspect Imaging Ltd.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO MN 55313

Re: K160185
Trade/Device Name: Wrist 3 MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, MOS
Dated: February 22, 2016
Received: February 23, 2016

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160185

Device Name
Wrist 3 MRI System

Indications for Use *(Describe)*
The Wrist 3 MRI System is intended for use as a magnetic resonance imaging device for producing axial, sagittal, coronal, and oblique images of the internal structure of the Wrist and Hand. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	February 16, 2016
Submitter:	Aspect Imaging Ltd. 27 Shaked St. Industrial Area Hevel Modi'in P.O. Box 926 Shoham, 6085001 ISRAEL
Primary Contact Person:	Israel A. Citron VP Quality Assurance and Regulatory Affairs Aspect Imaging LTD Tel: +972-73-223-9000 Ext 90 Fax: +972-3-716-5606 E mail: icitron@aspectimaging.com
Device Trade Name:	Wrist 3 MRI System
Common/Usual Name:	MRI System
Product Classification	II
Classification Name:	Magnetic Resonance Diagnostic Device (21 CFR 892.1000)
Product Code:	LNH, MOS
Predicate Device(s):	K130692 M2 Wrist 2 MRI System
Device Description:	The **Wrist 3 MRI System** is a 1Tesla Permanent MRI system producing MR images of the wrists and hands. During MRI scan, body parts to be imaged are held within a uniform static magnetic field, and are subject to sequences of RF pulses and gradient magnetic fields. The signal from the precession of the magnetization created by these fields is sampled and processed to produce image data.
Intended Use:	The **Wrist 3 MRI System** is intended for use as a magnetic resonance imaging device for producing axial, sagittal, coronal, and oblique images of the internal structure of the Wrist and Hand. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis

Technology: The **Wrist 3 MRI System** employs the same fundamental scientific technology as its predicate device (M2 Wrist 2 MRI System K130692).

Comparison of Specifications	Predicate Device M2 Wrist 2 MRI System (K130692)	Proposed Device Wrist 3 MRI System
Intended Use/Indication for Use	The **M2 Wrist II MRI System** is indicated for use as a magnetic resonance imaging device for producing transverse, sagittal and coronal images of the internal structure of the wrist (in patients with an arm length > 320 mm). When interpreted by a trained physician, the resultant MR images provide information that can be useful in determining a diagnosis.	The **Wrist 3** MRI System is intended for use as a magnetic resonance imaging device for producing axial, sagittal, coronal, and oblique images of the internal structure of the Wrist and Hand. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.
Patient Population	Patients requiring MR images of the wrist	Patients requiring MR images of the wrist and Hand
Anatomical Sites	Wrist	Wrist and Hand
Environment of Use	Hospital or clinical setting	Hospital or clinical setting
Energy Used and/or delivered	Magnetic Resonance	Magnetic Resonance
Human Factors	The M2 Wrist 2 MRI System is designed similar to other commercially available MRI Systems and therefore is familiar and easy for use for the user. Furthermore, the device contains a user-friendly software interface through which the user may easily access all device functions.	The Wrist 3 MRI System is designed similar to other commercially available MRI Systems and therefore is familiar and easy for use for the user. Furthermore, the device contains a user-friendly software interface through which the user may easily access all device functions.
Hardware Changes		
Magnet:		
- Physical Dimensions	125x87x82 cm	138x87x82 cm
- Bore opening	76x200 mm	85x220 mm
- Weight	1050 Kg	1300 (1700 with Trolley) Kg
- Field Strength	1 Tesla Permanent Magnet	1 Tesla Permanent Magnet
Gradient:		
-Strength	190 mT/m	215 mT/m
-Rise Time	0.475mSec	0.200mSec
-Slew Rate	400 T/m/Sec	1074 T/m/Sec
Computer:		
-Display:	24” LCD Desktop Display	15” Touch Display
RF Coils	1 Coil	2 Coils: Small/Large
Coil Type	TX/RX	TX/RX
Coil Geometry	Oval	Oval
Inner dimensions (mm)	50X108X86	60X100X169 / 75X135X192
Coil Design	Linear Volume	Linear Volume

Determination of Substantial Equivalence:

Summary of Nonclinical Testing:

The **Wrist 3 MRI System** and its applications were tested to comply with the below voluntary consensus standards.

- IEC/ES 60601-1
- IEC 60601-1-2
- IEC 60601-2-33
- NEMA MS-1
- NEMA MS-3
- NEMA MS-2
- NEMA MS-12
- NEMA MS-5

In addition System and Software verification and Validation testing were performed to demonstrate performance of the device as part of design controls activity.

The following design control activities were applied to the development of the system:

- Risk Management
- Requirements Management
- Design Reviews
- Unit level module verification
- System Integration verification
- Performance verification
- Safety and EMC testing
- Simulated use validation testing
- Sample clinical images

Summary of Clinical Tests:

The subject of this premarket submission, **Wrist 3 MRI System**, did not require clinical studies to support substantial equivalence.

Conclusion: Based on bench testing and sample clinical images, Aspect Imaging LTD believes that the **Wrist 3 MRI System** is substantially equivalent to its predicate device.